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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Examiner: Duffy, P. TECH CENTER 1600/2900

Heath et al.

Group Art Unit: 1645

Serial No.: 08/699,716

Atty Docket: 003/029/SAP

Filed: August 27, 1996

For: Recombinant F1-V Plague Vaccine

* * * * *

#29
Luda
8/20/02

RULE 1.131 DECLARATION

Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

We, Dr. David G. Heath, Dr. Arthur M. Friedlander, Dr.
George W. Anderson, Jr. and Dr. Susan L. Welkos, citizens of
the United States of America, do declare that:

1. We are the inventors of the above-referenced
application for patent filed on August 27, 1996;

2. Claims 1-3 and 5-17 of the above-referenced
application have been rejected over WO95/24475, (Titball et
al.-'75) publicly available on 14 September 1995.

3. We conceived and reduced to practice, in this
country, the invention claimed in the above-referenced
application prior to the publication date of Titball et al.
'75 document.

considered
11/1/02
200

Prior to 14 September 1995, an F1-V fusion protein consisting of all of F1 and all of V was produced by recombinant DNA technology and purified.

Prior to 14 September 1995, a mouse assay for testing the immunogenicity and protective efficacy of the recombinant F1-V fusion protein was initiated.

Eight groups of 10 mice each were immunized with the recombinant F1-V at 13.6 ug in alhydrogel, 27.2 ug in alhydrogel, V in alhydrogel as a control, and alhydrogel alone as a control. After the second immunization, antibody response was measured, and the mice were then challenged with either the C092 or the C12 strain of *Y. pestis* via aerosol or subcutaneous route. The days of survival after challenge were recorded.

Result details from Dr. Andersons's laboratory notebook showing the days of survival of each mouse in the assay are presented in Exhibit A pages 1 and 2. While the dates have been blocked out on Exhibit A, the work described therein was initiated prior to 14 September 1995. The results indicate that mice immunized with the recombinant F1-V fusion protein survived challenge with *Y. pestis*. Therefore, the recombinant F1-V fusion protein provides protection against challenge with *Y. pestis*.

In re Appln. of Heath et al. -- 08/699,716

5. We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of the title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 27 July 02

David G. Heath
Dr. David G. Heath

Date: 29 July 02

Arthur M. Friedlander
Dr. Arthur M. Friedlander

Date: 29 July 02

George W. Anderson
Dr. George W. Anderson

Date: 29 July 02

Susan L. Welkos
Dr. Susan L. Welkos

AUG 05 2002

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EXHIBIT A p. 1

Date:		Project: Recombinant F1-wholeV Fusion	
Institution: Yerkes prairie strain, C092 F1-V		Sex: female	
Route: SC	Dose:	Arrival:	at 7-8 wks
Animal strain: Swiss Webster		Vendor: Harlan Sprague Dawley	
Month:	Day:		
Day postinfection	LD50		
Group			
1 C12	Alhydrogel alone	No Chip	
2 C12	Alhydrogel 13.6ug F1-WV	No Chip	
3 C12	Alhydrogel 10ug Mauro-V	No Chip	
4 C12	Alhydrogel 13.6ug F1-WV	No Chip	
5 C12	Alhydrogel 27.2ug F1-WV	No Chip	
6 C12	Alhydrogel alone	No Chip	

For Animal Caretakers: Contact LTC Anderson, Office Ext 4933, Fax Ext 2152, Home (301) 473-5059 if you have any questions

Discard dead animals

Use scanner to check chip number of dead mice

Mark number of animals alive in each cage

re = mouse has been rechecked

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See page 79

Project: Recombinant F1-wholeV Fusion

Weekbook 5-27-39

① grains pastie strain, CO92 *M.E. Johnson*

1997

Done

Antivall

at 7-8wks

Vendor: Marian Sprague Dewley

Sex:	female
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Animal strain: Swiss Webster

Month Day

Day postinfection	
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Group	LP50
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7	CC-92
---	-------

- Alhydrogel

13.8ug

51-WV

8	Co92
---	------

Allyl alcohol

along

2136 Y.P.E.6

For Animal Caretakers: Contact LTC Anderson, Office Ext 4933, Fax Ext 2152, Home (301) 473-5058 if you have any questions

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